REMARKS

In the Office Action, claims 1, 2, 6-16 and 19-24 were rejected. By the present Response, claims 1, 6, 12, 15, 16, 19, and 24 are amended. Support for the amendment to claim 1, 6, 12, and 15 may be found in the specification on page 8, lines 1-7. Support for the amendments to claims 15, 16, and 19 may be found in the specification on page 4, line 15. The amendment to claims 24 clarifies certain aspects of this claim. Claims 21 and 23 are cancelled. Upon entry of the amendments, claims 1, 2, 6-16 , 19, 20, 22, and 24 will remain pending in the present patent application. Reconsideration and allowance of all pending claims are requested.

Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 15, 16, 19, 21, and 23 under U.S.C. § 112, first paragraph for containing subject matter which was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicants respectfully traverse this rejection.

Legal Precedent

First, regarding the written description requirement, the initial burden of proof regarding the insufficiency of the written description falls on the Examiner. Accordingly, the Examiner must present evidence or reasons why persons skilled in the art would not recognize a description of the claimed subject matter in the applicant's disclosure. *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q. 90, 96 (CCPA 1976). The Examiner is also reminded that the written description requirement does not require the claims to recite the same terminology used in the disclosure. The patentee may be his own lexicographer. *Ellipse Corp. v. Ford Motor Co.*, 171 U.S.P.Q. 513 (7th Cir. 1971), *aff'd.* 613 F.2d 775 (7th Cir. 1979), *cert. denied*, 446 U.S. 939 (1980). Moreover, any information contained

in any part of the application as filed, including the specification, claims and drawings, may be added to other portions of the application without introducing new matter. Accordingly, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 U.S.P.Q. 683 (Fed. Cir. 1985).

Rejection of claim 15, 16, 19, 21, and 23

In the Office Action, the Examiner specifically stated that the recitation "machine-readable medium" in claims 15, 16, and 19 was not supported by the original disclosure. Although the Applicants do not necessarily agree with the Examiner, claims 15, 16, and 19 have been amended and now recite a "processor-based system" Support for the amendments may be found in the specification on page 4, line 15. Applicants further note that the amendments clarified certain aspects of these claims and did not constitute a narrowing in scope. In view of the amendments, the Applicants consider the rejection of claims 15, 16, and 19 to be moot.

The Examiner specifically stated that the recitation "data related to an automatic software upgrade" was not supported by the original disclosure. While this claim has been cancelled, insofar as this may relate to claims 1, 6, 12, and 15, the Applicants point the Examiner to page 3, lines 19-20, of the specification, which discloses "A service provider may also be used to upgrade old software or load new software into the medical imaging system 22." In context, the related disclosure noted that service may be provided to a medical device to upgrade old software. Further, the specification states:

> The service report 64 has a second portion 68 that contains information related to the service performed on the medical imaging system 22. For example, in the illustrated embodiment, the second portion 68 comprises the class of

> the service performed, the field modification instruction code, the model number of the medical imaging system 22, the serial number of a part replaced during the service, the version of software upgraded or downloaded, and the total charge for the service performed on the medical imaging system.
>
> Specification, page 8, lines 1-7.

Here, the specification provides clear support for providing information (e.g., data) related to a software upgrade. As such, the recitations in claim 1, 6, 12, and 15 have adequate support in the specification and do not constitute new matter.

The Applicants have cancelled claim 23 and consider the rejection to be moot. For these reasons, the Applicants respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, and the objections to the specification.

Claim Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 22 and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. The Examiner noted that claim 22 recites "substantially contemporaneous." The Applicants note that this recitation is in claim 23, not claim 22. Accordingly, the Applicants believe that the rejection relates to claim 23, which has been cancelled. Further, Although Applicants do not necessarily agree with the Examiner's rejection of claim 24, the Applicants amended this claim as set forth above. In view of these amendments, the Applicants respectfully request the Examiner withdraw the rejection under to these claims under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 1, 6, 11-16, and 19-24 under 35 U.S.C. § 103(a) as unpatentable over Yokoi in view of "Virtual System Administrator" website accessed for the date of 24 April 2003 via http://web.archive.org/web/20030424123138/http://www.kaseya.com/ (hereinafter "Kaseya"). The Examiner also rejected claims 2 and 9 under 35 U.S.C. § 103(a) as unpatentable over Yokoi in view of Kaseya in view of Krasner U.S. Patent No. 5,825,327 (hereinafter "Krasner"). Further, claim 7 was rejected as being obvious over Yokoi in view of Kaseya, further in view of the FDA manual entitled "Quality Systems Manual," (hereinafter "the FDA Manual").

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish a *prima facie* case of obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, it is not sufficient to show that all the elements exist in the prior art, since a claimed invention composed of several elements may not be proved obvious merely by demonstrating each element was known, independently, in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* Specifically, there must be some articulated reasoning with a rational underpinning to support a conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and must be based on *objective evidence of record. In re Lee,* 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002).

Rejection of claims 1, 6, 11-16, and 19-24 based on Yokoi and Kaseya

In rejecting claims 1, 6, 11-16, and 19-24, the Examiner stated:

> However, Yokoi does not disclose that the device detects the alteration in the system or that the detection of the alteration is transmitted automatically. Kaseya discloses whereib a computer is operable to detect an alteration of software, and wherein the data transmitted automatically by the medical device is representative of the alteration (pages 1 and 2).
> It would have been obvious to one of ordinary skill in the art at the time if the invention to have modified the reporting system of Yokoi with the inclusion of the automatic detection of Kaseya in order to ensure the existence of the correct operation parameters within a medical device (Yokoi, column 8 lines 26-38).
> Office Action, pp. 6-7.

Applicants traverse this rejection and note that the combination of Yokoi and Kaseya does not disclose all the limitations of pending claims 1, 6, 11-16, and 19-24. The pending claims all include limitations that relate to a medical device that is operable to detect an alteration of at least one of medical device hardware and medical device software, wherein the alteration of the medical device software comprises a software upgrade, and where the medical device data transmitted automatically by the medical device is representative of the alteration to the medical device. While the Examiner correctly notes that Yokoi contains no such disclosure, Kaseya does not overcome the deficiency of Yokoi.

Kaseya relates to an auditing system that is a remote management system. Accordingly, the remote management may monitor several stations as part of a network and provide a list of software or hardware changes to a web-based browser system. While the Examiner notes that an instant notification may be provided when "a user installs a new application," Kaseya provides no teaching related to automatic notifications when software upgrades are installed.

Further, because the auditing function of Kaseya is remotely managed, Kaseya does not perform in a self-aware manner. While the Examiner has stated that that this phrase is not recited in the claims, the Applicants maintain that the recitations of the claims indicate that any software or hardware changes are automatically transmitted, e.g., to a remote monitor. This is consistent with a self-aware device. As stated in the specification:

> In the illustrated embodiment, the medical imaging system 22 is self-aware, i.e., the medical imaging system 22 inventories its software and hardware and automatically transmits service data representative of the change made to the software or hardware to the service center 28 when a change is made to the software or hardware. In this regard, the medical imaging system 22 is similar to a personal computer that has plug-and-play capability.
>
> Specification, p. 3, lines 28-31-p. 4, lines 1-3.

As recited in the pending claims, the medical device is capable of detecting any change or alteration, including software upgrades, in a self-aware manner. Because any change results in an automatic notification, the device is inherently self-aware.

Kaseya does not appear to disclose a medical device that automatically inventories hardware or software, including any software updates, in a self-aware manner. Thus, the combination of Tokoi and Kaseya does not yield the Applicants' claimed subject matter. Applicants respectfully request that the rejection of pending claims 1, 6, 11-16, and 19-20, 22, and 24 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of claims 2 and 9 based on Yokoi , Kaseya, and Krasner

In light of the amendments to independent claims 1 and 6, the rejection of claims 2 and 9 under 35 U.S.C. § 103(a) as unpatentable over Yokoi in view Kaseya further in view of Krasner is moot. Neither Yokoi nor Kaseya nor Krasner disclose a

limitation relating to a medical device being operable to communicate with a remote computer via a communication system, wherein the medical device is operable to detect a change in each of the hardware and the software, including software upgrades, and to automatically transmit a signal representative of the change to the remote computer. Accordingly, Applicants respectfully request withdrawal of the rejection of pending claims 2 and 9 under 35 U.S.C. § 103(a).

Rejection of claim 7 based on Yokoi, Kaseya, and the FDA Manual

In light of the amendments to independent claim 6, the rejection of claim 7 under 35 U.S.C. § 103(a) as unpatentable over Yokoi in view Kaseya further in view of the FDA Manual is moot. Neither Yokoi nor Kaseya nor the FDA Manual disclose a limitation relating to a medical device being operable to communicate with a remote computer via a communication system, wherein the medical device is operable to detect a change in each of the hardware and the software, including software upgrades, and to automatically transmit a signal representative of the change to the remote computer. Accordingly, Applicants respectfully request withdrawal of the rejection of pending claim 7 under 35 U.S.C. § 103(a).

Conclusion

In view of the remarks and amendments set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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